*Contains Nonbinding Recommendations*

**Draft Guidance on Dasatinib**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active ingredient:** Dasatinib

**Form/Route:** Tablet; Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 100 mg
   Subjects: Healthy males and non-pregnant females, general population.
   Additional Comments: Women of child bearing potential and nursing mothers should be excluded from the study given the potential for embryo-fetal toxicity and secretion of the drug into breast milk. Males and their female partners need to practice adequate contraception for at least one week after the last dasatinib dose.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in-vivo*
   Strength: 100 mg
   Subjects: Healthy males and non-pregnant females, general population.
   Additional Comments: Please see comments above.

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**Analytes to measure (in appropriate biological fluid):** Dasatinib in plasma

**Bioequivalence based on (90% CI)**: Dasatinib

**Waiver request of *in-vivo* testing:** 20 mg, 50 mg and 70 mg tablet, based on (i) acceptable bioequivalence studies on the 100 mg tablet, (ii) proportional similarity of the formulations across all strengths and (iii) acceptable *in vitro* dissolution testing of all strengths.

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.